AF/1645

PATENT TFW

UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 00-1278-C)

In the Application of:	
Lawton *et al.*	**Art Unit: 1645**
Serial No.: 10/054,647	**Examiner: Ford, V.**
Filed: January 22, 2002	**Conf. No. 9151**
For: Compositions and Methods for Detection of *Ehrlichia canis* and *Ehrlichia chaffeensis* Antibodies	

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In regard to the above identified application,

1. We are transmitting herewith the attached:
   a) Request for Reconsideration Under 37 CFR §41.52 Appeal No. 2005-1593;
   b) Return postcard

2. With respect to fees:
   It is believed no fee is due at this time.

3. GENERAL AUTHORIZATION: Please charge any additional fees or credit overpayment to Deposit Account No. 13-2490. A duplicate copy of this sheet is enclosed.

4. CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1, are being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 22, 2006.

Respectfully submitted,

Date: February 22, 2006

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the Application of:	
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For: Compositions and Methods for Detection of *Ehrlichia canis* and *Ehrlichia chaffeensis* Antibodies	Atty. Docket No.: 00-1278-C

REQUEST FOR RECONSIDERATION UNDER 37 CFR §41.52
APPEAL NO. 2005-1593

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REQUEST FOR RECONSIDERATION UNDER 37 CFR §41.52
APPEAL NO. 2005-1593

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellants respectfully request reconsideration of the Board Decision of December 23, 2005 in the above-mentioned Appeal. The Commissioner is authorized to charge our Deposit Account No. 13-2490 for any fee that is due in connection with this filing.

Contents

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REAL PARTY IN INTEREST

The real party in interest is IDEXX Laboratories, Inc., Westbrook, Maine, to whom this invention is assigned.

RELATED APPEALS AND INTERFERENCES

Appeal number 2005-1610 (U.S. Ser. No. 10/054,354) and Appeal number 2005-2708 (U.S. Ser. No. 09/765,739) are related to this appeal. Applicant is aware of no other related appeals, interferences, or judicial proceedings concerning this application.

STATUS OF CLAIMS

Claims 1-13 are pending and stand rejected. A copy of the claims is attached in Appendix A.

SUMMARY OF THE INVENTION

A summary of the invention can be found in the appeal brief.

SUMMARY OF BOARD'S DECISION

The Board reversed the rejections for claim indefiniteness, lack of written description, and enablement. The rejection of claims 1-13 for anticipation was affirmed.

GROUNDS OF REJECTION TO BE REVIEWED IN REQUEST FOR REHEARING

Claims 1-13 stand rejected under 35 U.S.C. §102(a) as allegedly anticipated by Rikihisa *et al.* WO 99/13720 ("Rikihisa"). Appellants request reconsideration of the rejection of claims 1-13 for anticipation.

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ARGUMENT

I. Claims 10-13 are novel over Rikihisa under 35 U.S.C. §102(a)

Claims 1-13 stand rejected under 35 U.S.C. §102(a) as allegedly anticipated by Rikihisa *et al.* Applicants respectfully request reconsideration of this rejection.

The Board decision asserts that Appellants did not argue individual claims separately. The Board, therefore, did not consider claims 10-13 individually. In the Reply Brief, however, Appellants did indeed argue claims 10-13 separately. *See*, Reply Brief, pages 16-17.

In particular, Appellants argued that Claims 10-13 recite a composition of matter comprising an isolated polypeptide that is 20 amino acids in length . . . that specifically binds to an anti-*Ehrlichia* antibody. The claims are therefore limited to polypeptides that are 20 amino acids in length. As such, the claims cannot read on the whole *Ehrlichia* proteins of Rikihisa.

This position is consistent with the handling of claims 7-8 in related Appeal No. 2005-1610. In Appeal No. 2005-1610 claims 7-8 also recite isolated polypeptides that are 20 amino acids in length, and which comprise SEQ ID NO:1 or amino acid substitution variants thereof, wherein the polypeptides specifically bind to an anti-*Ehrlichia* antibody. These claims were not rejected over the Rikihisa reference, and the same holding should apply to Claims 10-13 of the present application. Claims 10-13 are novel and unobvious over Rikihisa. Appellants respectfully request withdrawal of the rejection.

II. Claims 1-13 are novel over Rikihisa under 35 U.S.C. §102(a)

A. The Board's Interpretation of *PPG Indus. Inc. v. Guardian Indus. Corp.*

The Board states that "absent a clear indication in the specification or claims of what the basic and novel characteristics of SEQ ID NO:2 actually are the 'consisting essentially of' in claim 1 will be construed as equivalent to 'comprising.'" *See*, Board Decision, page 17. The Board cites *PPG Indus. Inc. v. Guardian Indus. Corp.* to support

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this position.[1] 156 F3d 1351, 1355, 48 USPQ2d 1351, 1355 (Fed. Cir. 1998). However, the facts in this case are diametrically opposite the facts in *PPG Indus.*

In *PPG Indus.* the issue was whether Guardian's glass composition infringed PPG's claims in U.S. Patent Number 5,240,886 (the '886 patent). Claims of the '886 patent recite a green tinted, ultraviolet absorbing glass having a base glass composition consisting essentially of certain amounts of specific chemical compounds and a colorant portion consisting essentially of certain amounts of specific chemical compounds.[2]

Guardian defended against the claim of infringement by arguing that their glass contained iron sulfide, an ingredient unlisted in PPG's claims or specification, as a colorant. 156 F3d at 1353, 48 USPQ2d at 1353. One issue was whether PPG defined the scope of the phrase "consisting essentially of" for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention. The court found that the patent was silent about the inclusion of iron sulfide in the claimed glass compositions and about what constitutes a material effect on the properties of the glass. 156 F3d at 1356, 48 USPQ 2d at 1356.

The instant application, however, makes crystal clear that the claimed polypeptides are distinctly different from whole *Ehrlichia* proteins. In Example 1, the specification provides a working example that compares the sensitivity and specificity of polypeptides of SEQ ID NO:1 and SEQ ID NO:2 in contrast to the sensitivity and specificity of whole, partially purified *Ehrlichia* proteins. In the testing of 70 samples,

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[1] The Board cites *PPG Indus. Inc. v. Guardian Indus. Corp.*, 75 F3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996). However, Appellants believe that the Board intended to cite *PPG Indus. Inc. v. Guardian Indus. Corp.*, 156 F3d 1351, 1355, 48 USPQ2d 1351, 1355 (Fed Cir. 1998).

[2] Claim 1 reads as follows:

A green tinted, ultraviolet absorbing glass having a base glass composition consisting essentially of:

SiO_2	68-75 weight %
Na_2O	10-20
CaO	5-15
MgO	0-5
Al_2O_3	0-5
K_2O	0-5

and a colorant portion consisting essentially of:

CeO_2	Less than 0.5 weight %
Total Iron (as Fe_2O_3)	Greater than 0.85 weight %
FeO/total iron	Less than 0.275

exhibiting ultraviolet transmittance no greater than 31 percent (300 to 390 nanometers) and luminous transmittance (illuminant A) of at least 70 percent, both at a reference thickness of 3.9 millimeters.

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the polypeptides of SEQ ID NO:1 and SEQ ID NO:2 exhibited a sensitivity of 98.5% and a specificity of 100% in contrast to the whole, partially purified *Ehrlichia* proteins, which exhibited a sensitivity of 75.3% and a specificity of only 60%. *See,* specification, paragraph spanning page 20 and 21. This working example shows squarely that the whole *Ehrlichia* protein was not included in the claimed invention. *See also*, page 2, line 21 through page 3, line 2, of the specification, which noted that more highly purified reagents are needed to construct more accurate assays for *Ehrlichia.*

Furthermore, the declaration of Dr. Chandrashekar confirms that the claimed polypeptides are more sensitive and specific than whole *Ehrlichia* proteins. *See,* paragraphs 2-3 and 6-7 (of record).

Example 1 of the specification made clear that use of the whole *Ehrlichia* proteins would materially and negatively affect the basic and novel characteristics of the claimed polypeptides. That is, use of whole *Ehrlichia* proteins would result in assays that are less sensitive and less specific than those disclosed in the instant specification. The specification made this distinction clear, unlike the situation in *PPG Indus.* where the specification was left wide open as to whether the addition of iron sulfide would effect the claimed composition. As such, the claims cannot be read so that the claimed isolated polypeptides encompass whole *Ehrlichia* proteins.

In *PPG Indus.* no error in was found the district court's decision stating that an ingredient has a material effect on the characteristics of the glass "if the effect is of importance or of consequence to those of ordinary skill in the art of glass making." 156 F3d at 1354, 48 USPQ2d at 1354. In the instant case, one of ordinary skill in *Ehrlichia* antibody detection would consider a reduction in specificity and sensitivity due to the use of whole *Ehrlichia* proteins instead of the polypeptides of the instant invention to be of importance. *See, e.g.,* declaration of Dr. Chandrashekar, paragraphs 2-3 and 6-7 (of record).

The Appellant has met their burden of showing that the introduction of additional steps or components would materially change the characteristics of the invention. *See, In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). The specification clearly demonstrates that inclusion of amino acids (*e.g.* additions that result in the whole protein) to the claimed polypeptides, which are fragments of whole proteins, would be detrimental

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to the sensitively and specificity of assays for detection of *Ehrlichia* antibodies. One of skill in the art would find a reduction in sensitivity and specificity to be of importance. *See,* declaration of Dr. Chandrashekar, paragraphs 2-3 and 6-7 (of record). Therefore, the claims do no read on the whole proteins of Rikihisa.

B. The Board's Interpretation of *In re Crish*

The Decision on Appeal, page 18, nt. 2, cites *In re Crish* to support the argument that the claims read on whole *Ehrlichia* proteins. 393 F.3d 1253, 1256, 73 USPQ 1364, 1367 (Fed. Cir. 2004). If the Board reconsiders and accept Appellants' position distinguishing the *PPG Indus.* decision, then it should follow that nothing more need be said to distinguish *In re Crish.*

In an abundance of caution, however, Appellants note that the citation of *In re Crish* is seriously misplaced. A representative claim on appeal in Crish is reproduced below:

> 53. A purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO:1, wherein said portion consists of the nucleotide sequence from 521 to 2473 of SEQ ID NO:1, and wherein said portion of the nucleotide sequence of SEQ ID NO:1 has promoter activity.

The key point is that the patent claim at issue *In re Crish* included both phrases "comprising at least a portion" as well as "consists of." For this reason, the Federal Circuit held that the "comprising at least a portion" phrase left the claim open ended, notwithstanding that the "consist of" phrase seemed to close a portion of the claim.

That circumstance has absolutely nothing to do with the present appeal, because the claims in the present case do not include the phrase "comprising at least a portion." Equally important, *In re Crish* does not and cannot be cited for the proposition that the phrase "consists of" may properly be equated to the phrase "comprising." Appellants request that the Decision be corrected in this regard.

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Summary

Applicants respectfully submit that the claims 1-13 are in a condition for allowance.

Respectfully submitted,

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APPENDIX A

CLAIMS AS PENDING

1. (Previously Presented) A composition of matter comprising an isolated polypeptide consisting essentially of SEQ ID NO:2 or a phenotypically silent amino acid substitution variant thereof that specifically binds to an anti-*Ehrlichia* antibody.

2. (Previously Presented) The composition of claim 1, further comprising a carrier.

3. (Previously Presented) An article of manufacture comprising packaging material and, contained within the packaging material, a polypeptide comprising the polypeptide consisting essentially of SEQ ID NO:2 or a phenotypically silent amino acid substitution variant thereof that specifically binds to an anti-*Ehrlichia* antibody.

4. (Previously Presented) The article of manufacture of claim 3 wherein the packaging material comprises a label that indicates that the polypeptide can be used for the identification of *Ehrlichia* infection in a mammal.

5. (Previously Presented) The article of manufacture of claim 4, wherein the label indicates that identification of an *Ehrlichia* infection is done using a method of detecting presence of antibodies to *Ehrlichia* comprising:

(a) contacting a polypeptide the polypeptide consisting essentially of SEQ ID NO:2 or a phenotypically silent amino acid substitution variant of the polypeptide consisting essentially of SEQ ID NO:2 that specifically binds to an anti-*Ehrlichia* antibody, with a test sample suspected of comprising antibodies to *Ehrlichia*, under conditions that allow polypeptide/antibody complexes to form; and

(b) detecting polypeptide/antibody complexes;

wherein the detection of polypeptide/antibody complexes is an indication that an *Ehrlichia* infection is present.

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6. (Previously Presented) The article of manufacture of claim 4, wherein the *Ehrlichia* infection is caused by *Ehrlichia canis* or *Ehrlichia chaffeensis*.

7. (Previously Presented) A composition of matter comprising an isolated polypeptide consisting essentially of SEQ ID NO:2 or a conservative amino acid substitution variant thereof that specifically binds to an anti-Ehrlichia antibody.

8. (Previously Presented) An article of manufacture comprising packaging material and, contained within the packaging material, a polypeptide comprising the polypeptide consisting essentially of SEQ ID NO:2 or a conservative amino acid substitution variant thereof that specifically binds to an anti-*Ehrlichia* antibody.

9. (Previously Presented) The article of manufacture of claim 4, wherein the label indicates that identification of an *Ehrlichia* infection is done using a method of detecting presence of antibodies to *Ehrlichia* comprising:

(a) contacting a polypeptide comprising the polypeptide consisting essentially of SEQ ID NO:2 or a conservative amino acid substitution variant of the polypeptide consisting essentially of SEQ ID NO:2 that specifically binds to an anti-*Ehrlichia* antibody, with a test sample suspected of comprising antibodies to *Ehrlichia*, under conditions that allow polypeptide/antibody complexes to form; and

(b) detecting polypeptide/antibody complexes;

wherein the detection of polypeptide/antibody complexes is an indication that an *Ehrlichia* infection is present.

10. (Previously Presented) A composition of matter comprising an isolated polypeptide that is 20 amino acids in length, which comprises SEQ ID NO:2 or a phenotypically silent amino acid substitution variant thereof that specifically binds to an anti-*Ehrlichia* antibody.

11. (Previously Presented) The composition of claim 10, further comprising a carrier.

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12. (Previously Presented) A composition of matter comprising an isolated polypeptide that is 20 amino acids in length, which comprises SEQ ID NO:2 or a conservative amino acid substitution variant thereof that specifically binds to an anti-*Ehrlichia* antibody.

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Summary

Applicants respectfully submit that the claims 1-13 are in a condition for allowance.

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Date: 2-22-06 by: _____

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